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RESEARCH**

***APPLICATION NUMBER:***  
**20-748**

**PHARMACOLOGY REVIEW**

DEC 16 1999

**REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA**

**KEY WORDS**

Reviewer Name: Kumar D. Mainigi

Division Name: Dermatologic and Dental Drug Products, HFD-540

Review Completion Date: 12-16-1999

Electronic file number:

**NDA 20-748 (Amended)**

Original Amendment/09-08-1999

Information to Sponsor

Sponsor: Galderma Laboratories, Inc.

3000 Alta Mesa Blvd., Suite 300

Fort Worth, TX 76133

**Drug:** Code Names: CD271; AL02866

Trade Name: DIFFERIN™ (adaplene cream) Cream 0.1%

Chemical Name: 6-[3-(1-Adamantyl)-4-methoxyphenyl]-2-napthoic acid

CAS Registry Number:

Molecular Formula/Molecular weight:

Structure:

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**Related Submissions:**

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**NDA 20-338 (0.1% Solution), Owen/Galderma Laboratories, Inc., Fort Worth, TX**  
(approved May 1996)

**20-380 (0.1% Gel), Owen/Galderma Laboratories, Inc., Fort Worth, TX**  
approved May 1996)

**Drug class:** Napthoic acid class of anti-acne agent

**Indication:** Treatment of acne vulgaris

**Background:** In a letter dated July 9, 1998, the sponsor was informed that because of the inadequate information provided under the Clinical/Statistical, Biopharmaceutics, and Microbiology sections, the NDA 20-748 was not approvable. According to the sponsor, in this amendment, all the major deficiencies have been corrected. The human pharmacokinetic and the clinical sections in draft labeling have also been revised.

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**Regulatory conclusions:** The non-clinical safety section and the corresponding labeling draft were approved under the original submission (review dated 5-November 1997), therefore, at this stage, no further action is required.

**Regulatory Recommendations:** None

LSI

Kumar D. Mainigi, Ph.D., M.P.H., D.A.B.T.  
Toxicologist

CC: Original NDA 20-748  
HFD-82  
HFD-540  
MO/Huene  
Pharm/Mainigi  
PM/Cintron  
Micro/Greenman  
Chem/Timmer  
Biopharm/Lee

Concurrence:  
A.Jacobs, TL, HFD-540  
J.Wilkin, Dir HFD-540

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